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Nazari

(10) **Patent No.: US 9,463,071 B2**
(45) **Date of Patent: Oct. 11, 2016**

(54) **THERAPEUTIC SKIN LIFTING DEVICE AND RELATED SYSTEMS AND METHODS**

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(21) Appl. No.: **14/743,844**

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Related U.S. Application Data

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(60) Provisional application No. 61/685,545, filed on Mar. 20, 2012, provisional application No. 61/685,752, filed on Mar. 22, 2012, provisional application No. 61/690,106, filed on Jun. 19, 2012.

(51) **Int. Cl.**
A61H 1/00 (2006.01)
A61F 13/10 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 19/24*** (2013.01); ***A61F 5/0118*** (2013.01); ***A61F 13/00987*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61F 13/02; A61F 5/0118; A61F 13/0276; A61F 13/10; A61B 19/24; A61L 15/16; A61L 15/58
USPC 601/1
See application file for complete search history.

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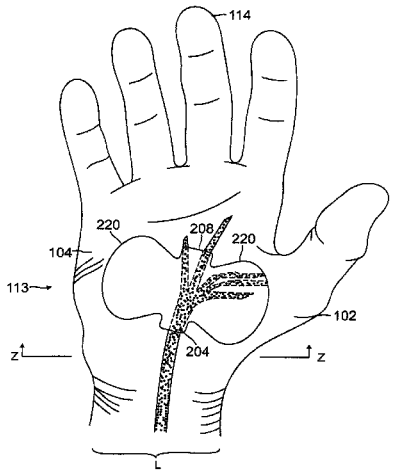
(57) **ABSTRACT**

A therapeutic device has a bridge portion adapted for releasable adherence to a patch of skin so as to lift the patch of skin above a sensitive underlying treatment site in reducing discomfort or pain associated with tissue compression at the treatment site. The bridge portion is elevated above the treatment site with an exposed adhesive facing the patch of skin to be lifted and/or stretched outwardly. With the application of pressure to elastically deform the device from its original neutral configuration, the bridge portion is brought into contact with the patch of skin, adhering the skin to the adhesive. When the pressure is removed, the device rebounds and generally reassumes its original configuration with the bridge portion lifting the attached patch of skin.

9 Claims, 13 Drawing Sheets



(51) **Int. Cl.**

A61B 19/00	(2006.01)
A61F 13/12	(2006.01)
A61F 13/00	(2006.01)
B29C 69/00	(2006.01)
A61F 5/01	(2006.01)
A61F 13/02	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 13/0276*** (2013.01); ***A61F 13/10*** (2013.01); ***A61F 13/122*** (2013.01); ***A61H 1/008*** (2013.01); ***B29C 69/005*** (2013.01); *A61F 2013/0028* (2013.01)

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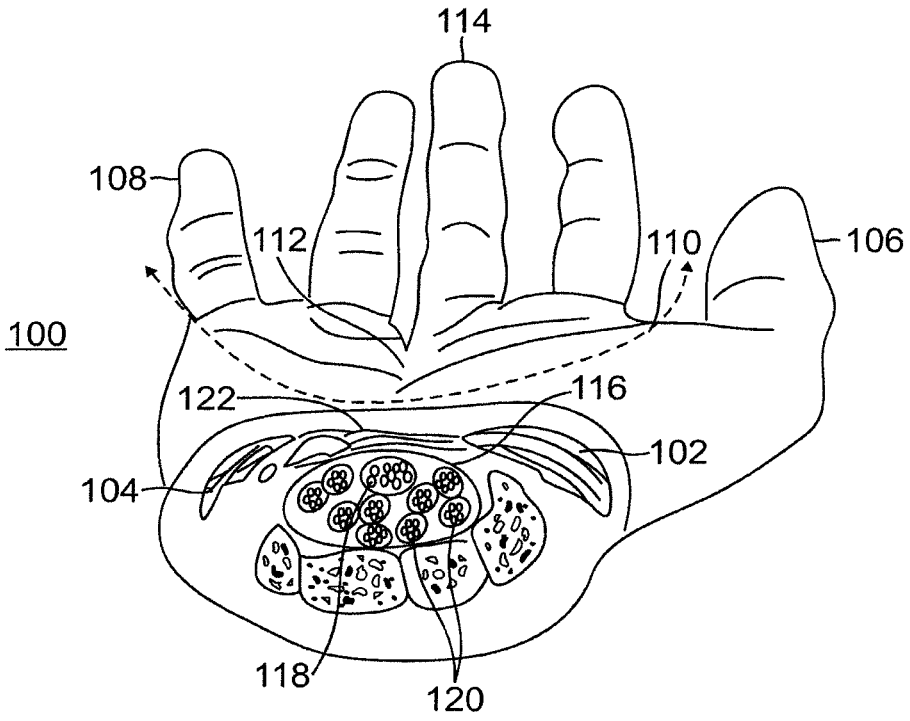


FIG. 1

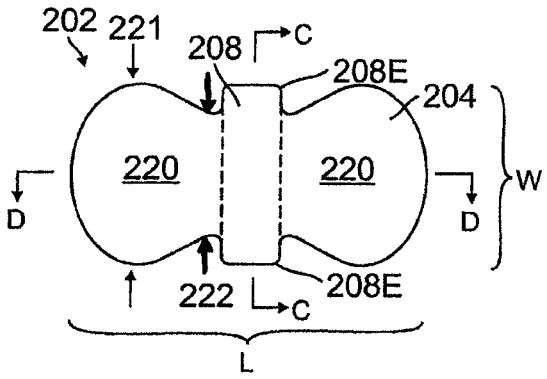


FIG. 2A

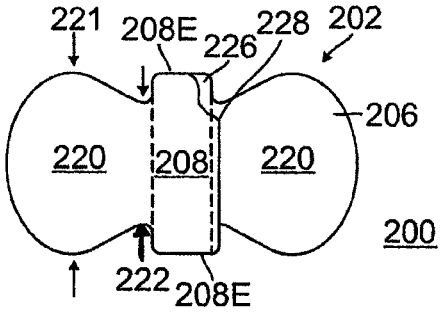


FIG. 2B

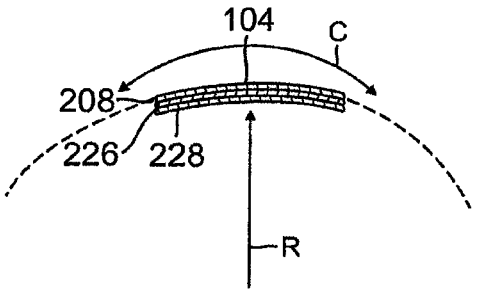


FIG. 2C

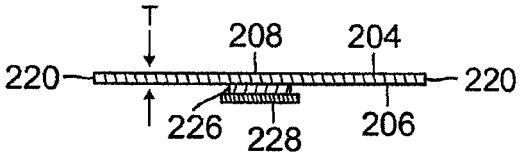


FIG. 2D

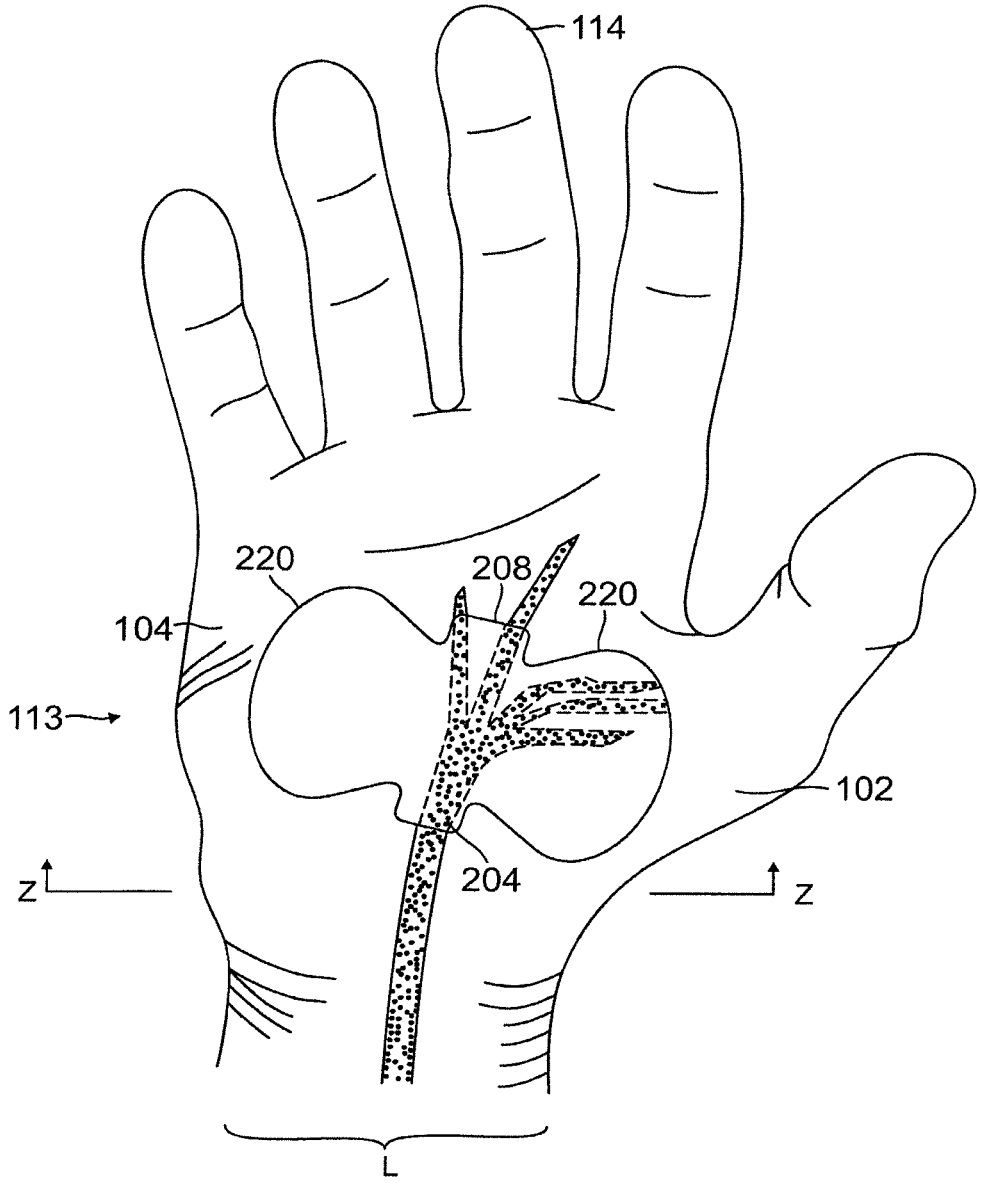


FIG. 3

FIG.3A

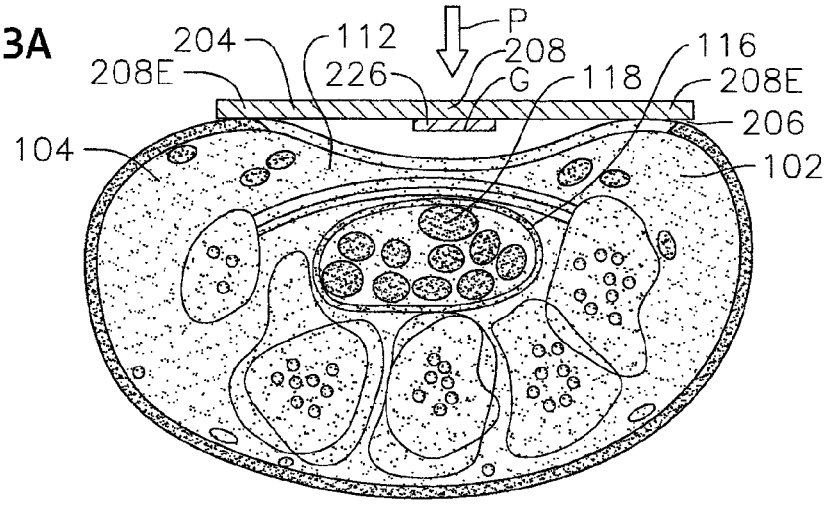
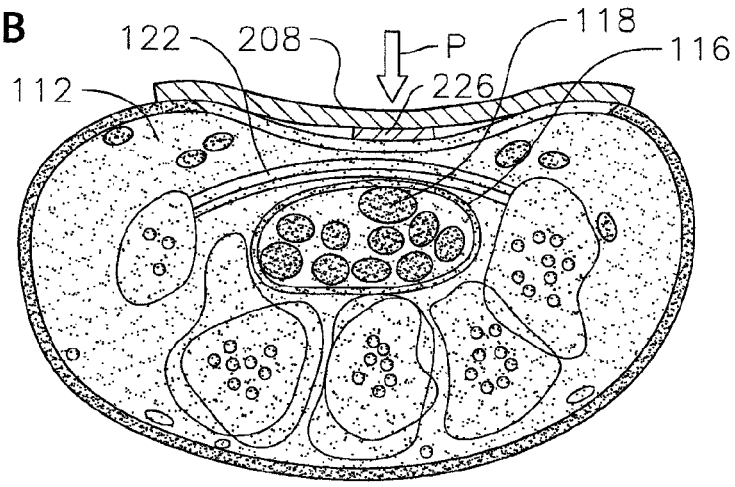


FIG.3B



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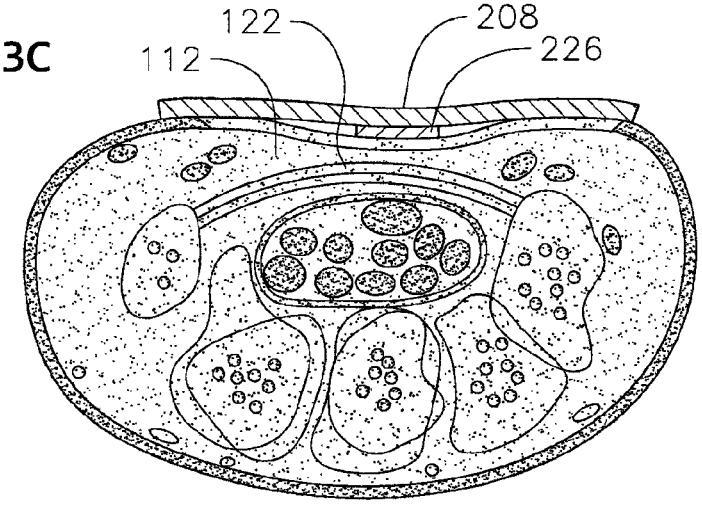


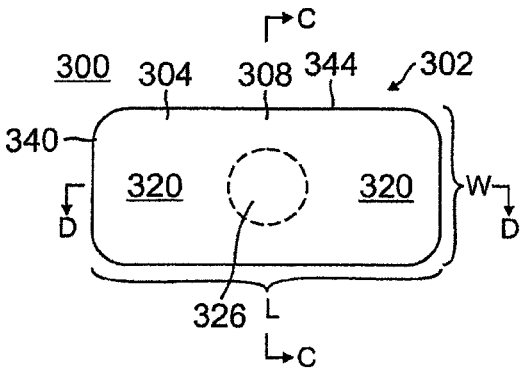
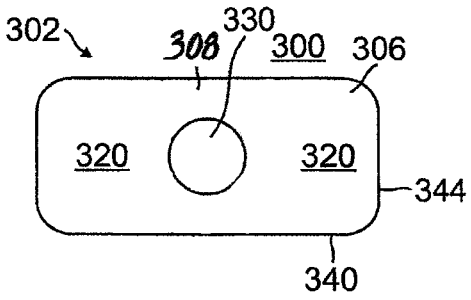


FIG. 4A



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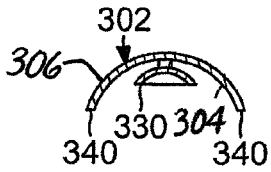

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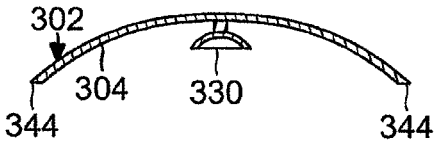

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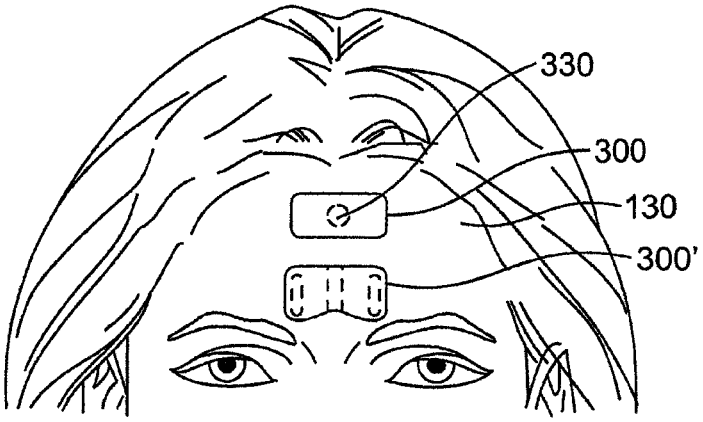

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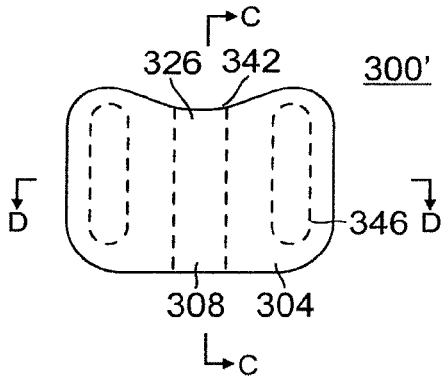
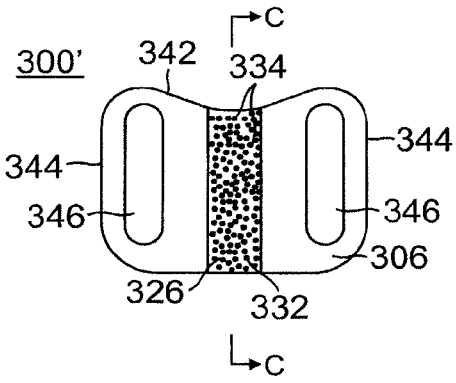


FIG. 5A



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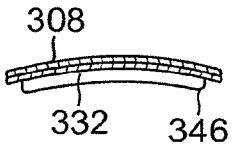

FIG. 5C

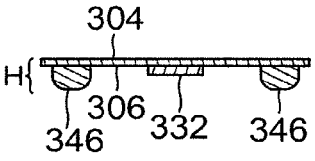

FIG. 5D

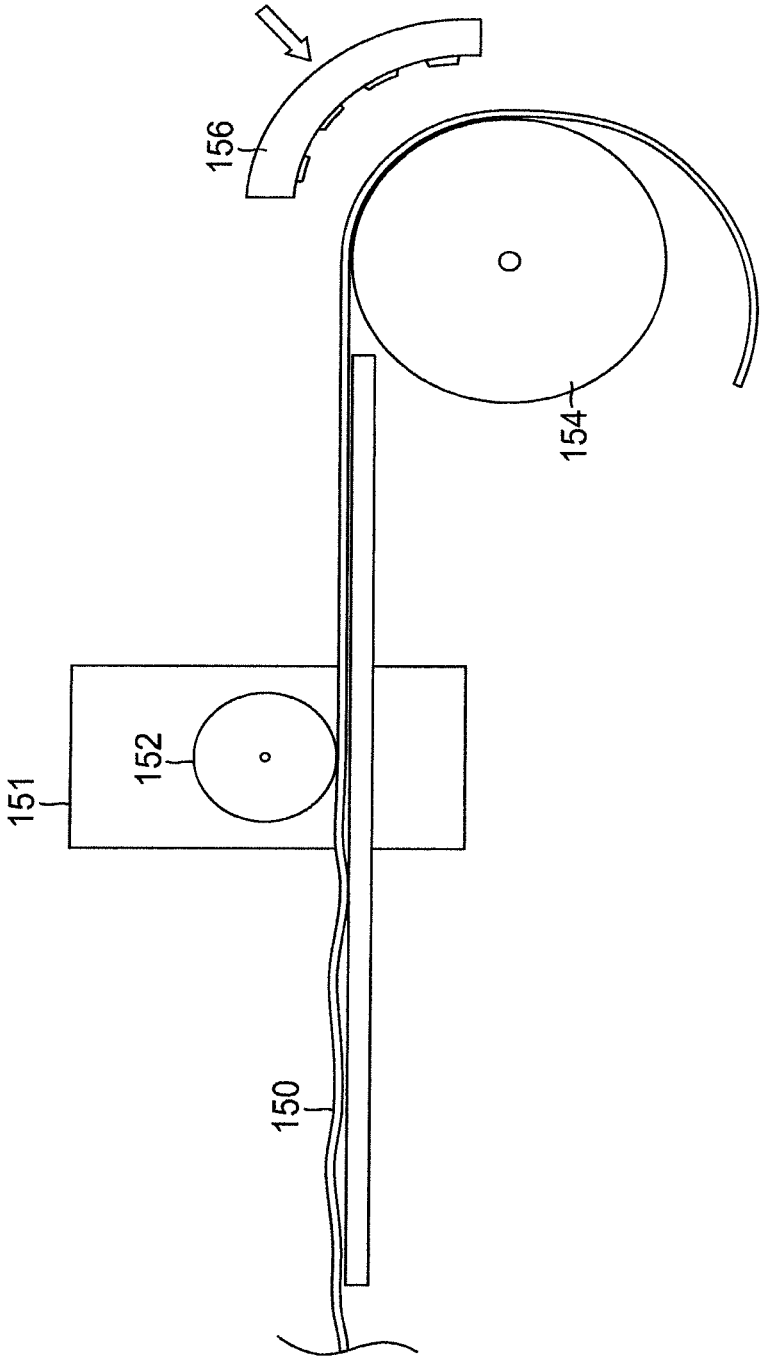

FIG. 7

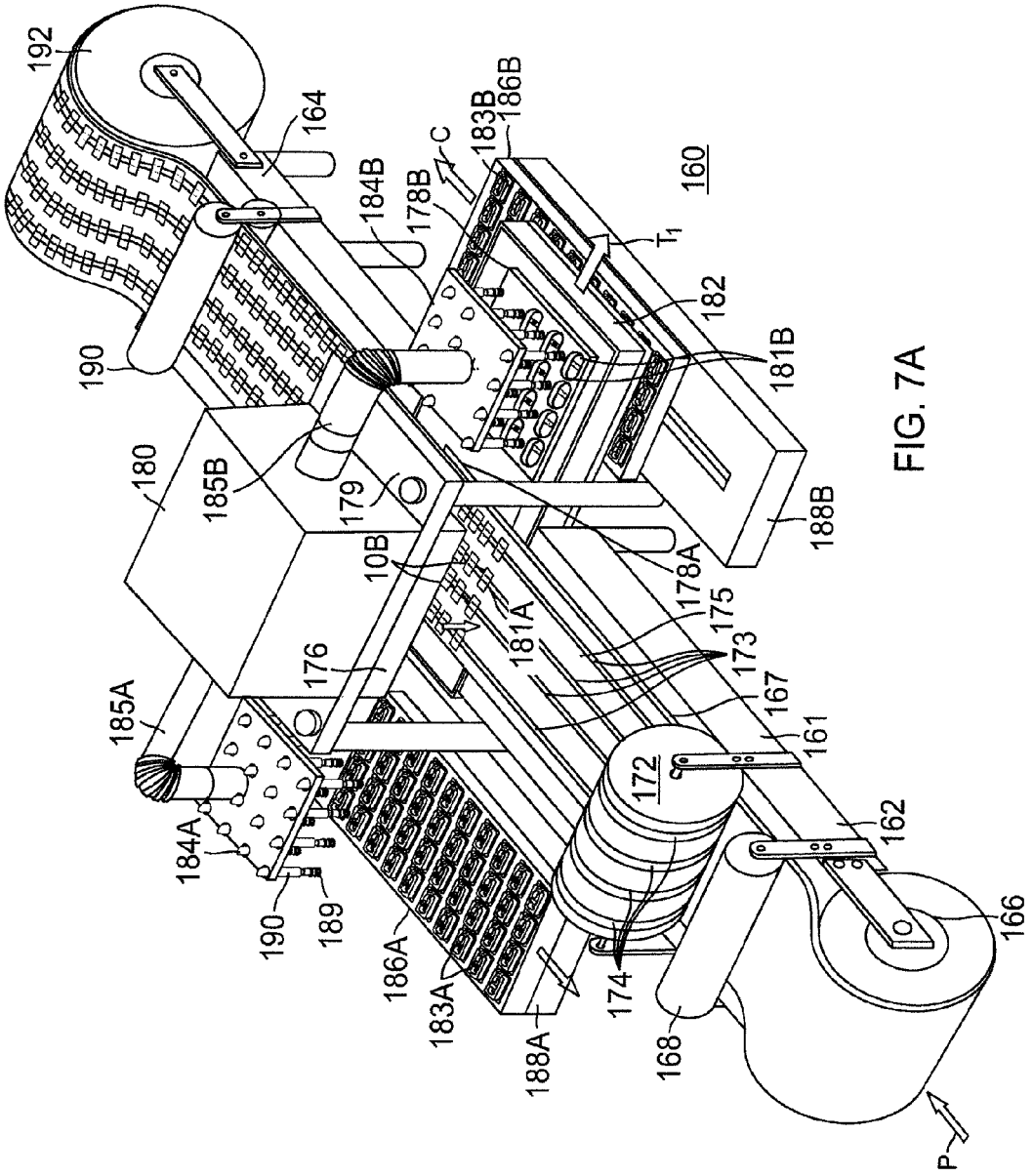
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FIG. 7A

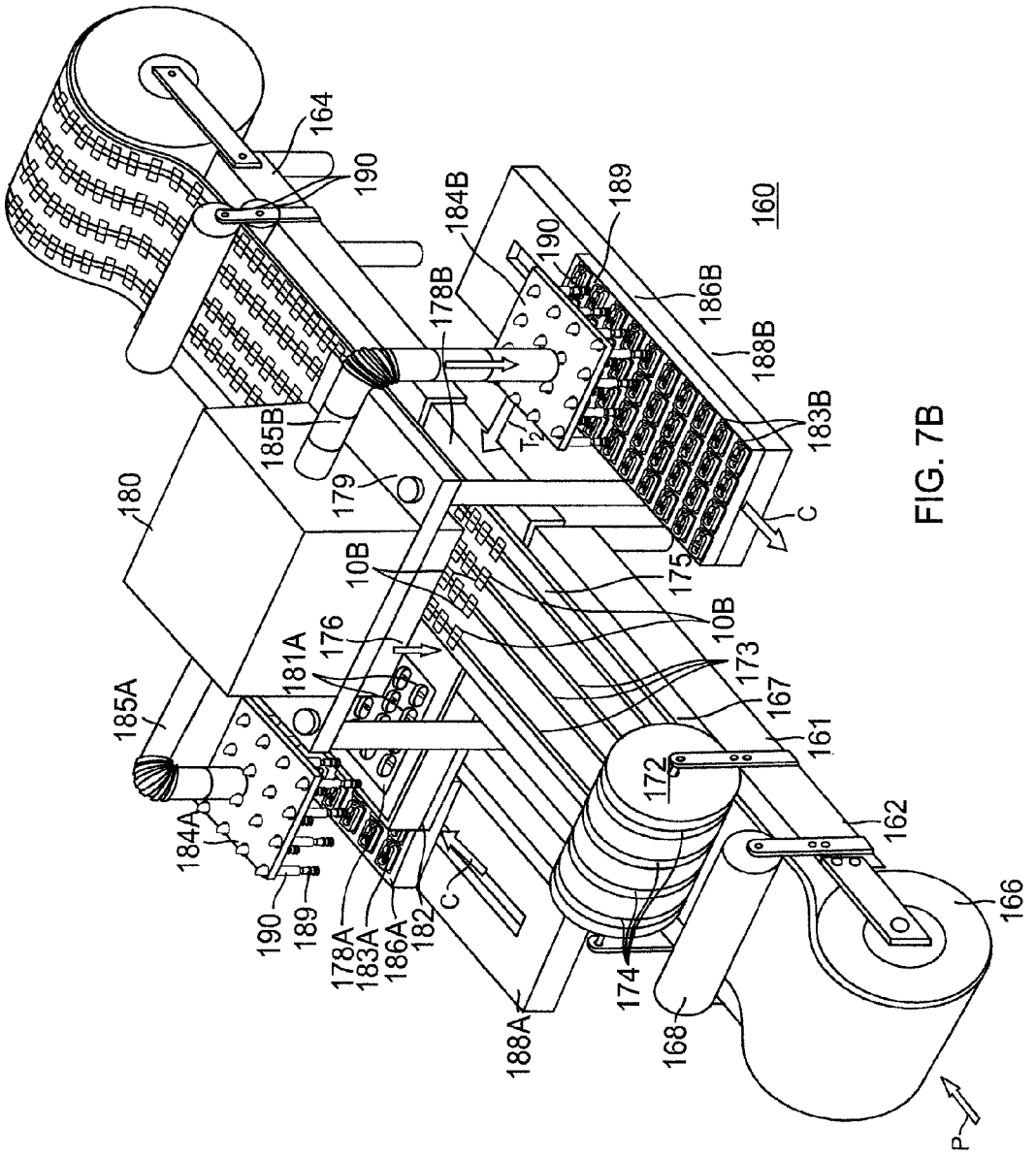
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FIG. 7B

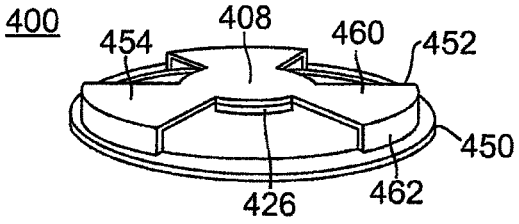


FIG. 8A

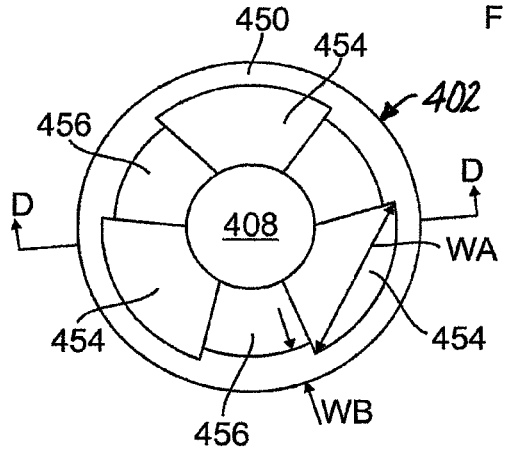


FIG. 8B

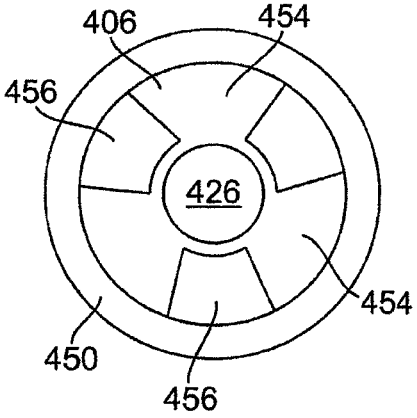


FIG. 8C

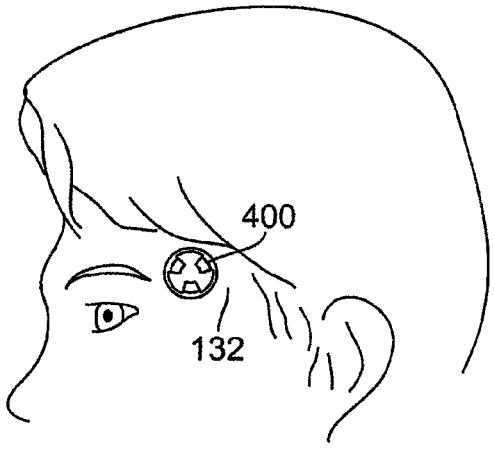
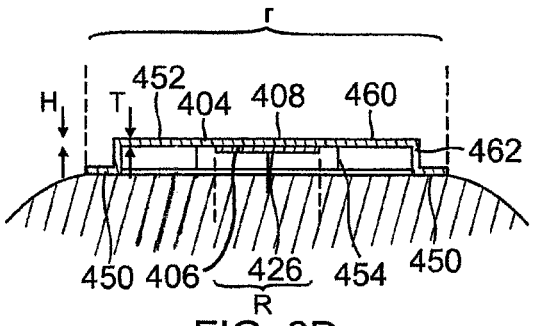


FIG. 9



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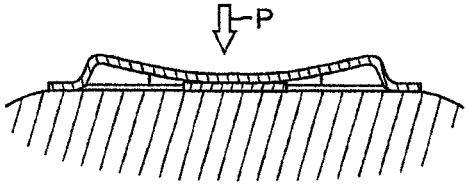

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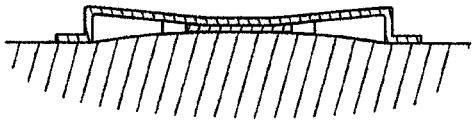

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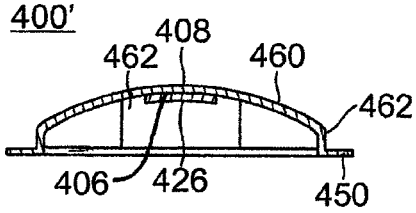

FIG. 8G

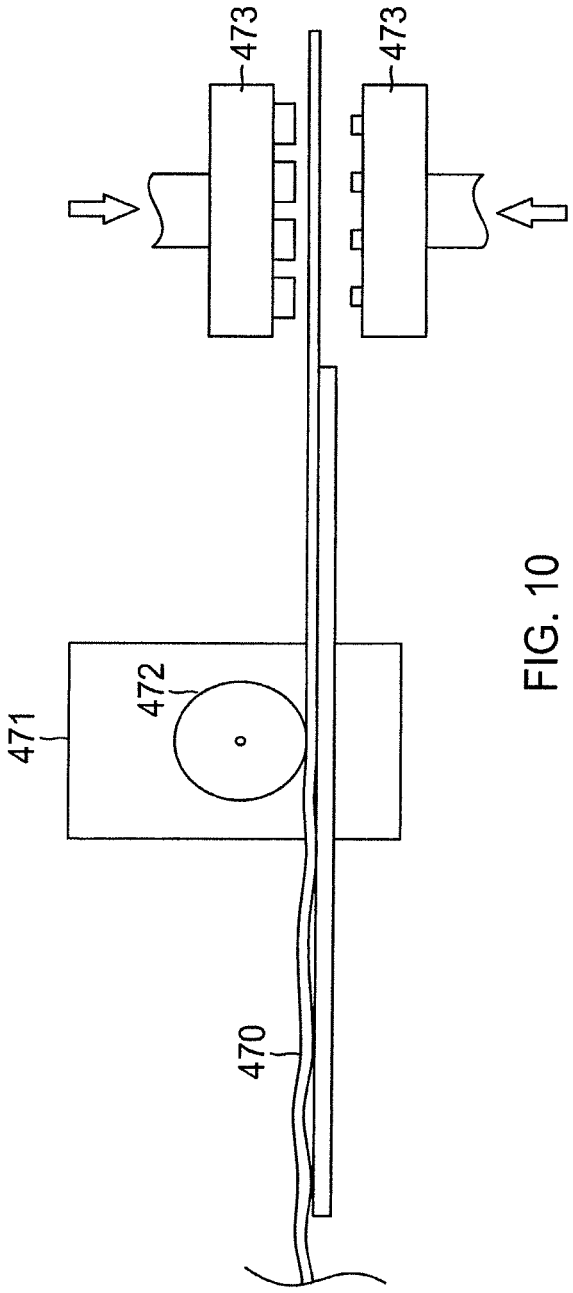

FIG. 10

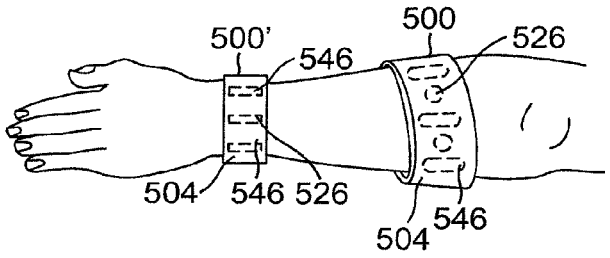

FIG. 12

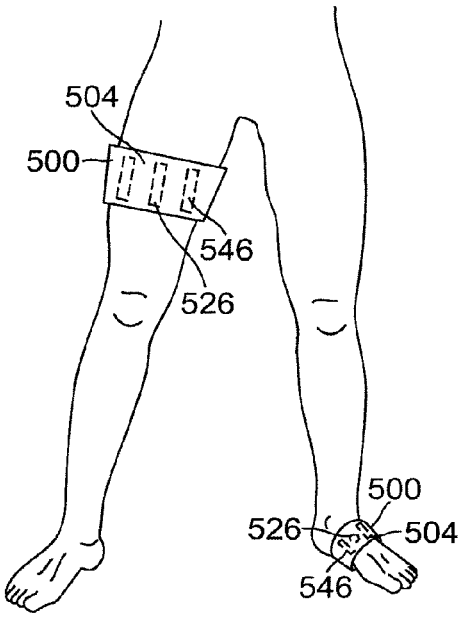

FIG. 13

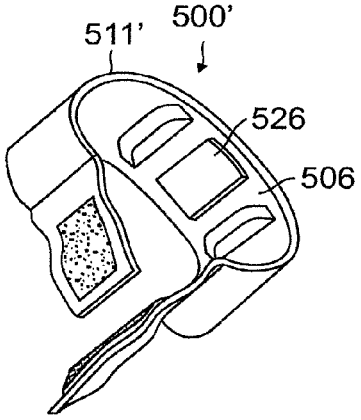

FIG. 14

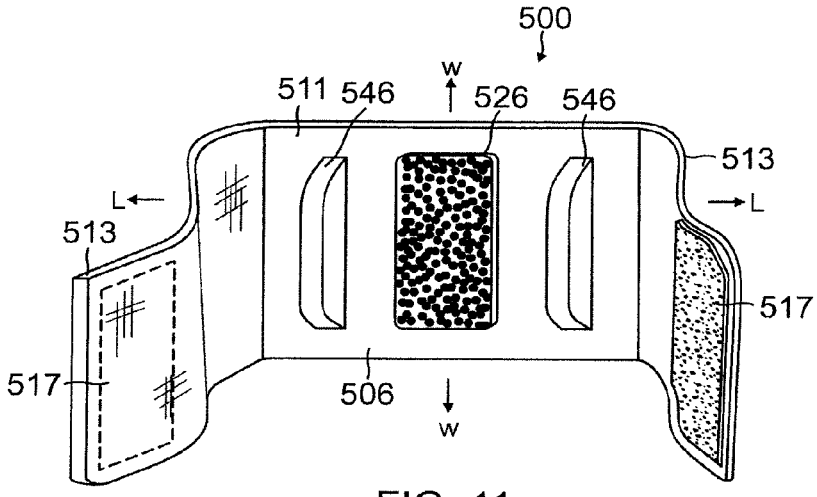

FIG. 11

THERAPEUTIC SKIN LIFTING DEVICE AND RELATED SYSTEMS AND METHODS

RELATED APPLICATIONS

This application is a continuation application of U.S. patent application Ser. No. 13/825,759 filed Mar. 22, 2013, which is a National Phase Patent Application of International Application Number PCT/US20131028099, filed on Feb. 27, 2013, which claims the benefit of the filing dates of U.S. Provisional Application Ser. Nos. 61/685,545, filed Mar. 20, 2012; 61/685,752 filed Mar. 22, 2012; and 61/690,106 filed Jun. 19, 2012, the entire contents of which are incorporated herein by reference.

FIELD OF INVENTION

The present invention relates to a medical device for reducing symptoms of physical ailments and conditions, including pain and discomfort associated with Carpal Tunnel Syndrome (CTS), migraine headaches and other pressure-related ailments and conditions.

BACKGROUND

Carpal Tunnel Syndrome (CTS) is idiopathic median neuropathy at the carpal tunnel of a human hand. With reference to FIG. **1**, a human hand **100** is illustrated with muscles in a proximate portion, below thumb **106** and pinky finger **108**, including abductor pollicis brevis **102** and abductor digit minimi **104**, respectively. The muscles **102** and **104** define transverse carpal arch **110** with a recess **112** therebetween that is generally aligned with third finger **114**. In tissues below the recess **112** is carpal tunnel **116** where median nerve **118** enters the hand **100**. This tunnel is normally narrow as it is also occupied by flexor tendons **120**, so any swelling of adjacent tissue, including the flexor retinaculum ligament **122**, can pinch the nerve and cause pain, numbness, tingling or weakness.

The pathology of CTS is not completely understood but can be considered compression of the median nerve traveling through the carpal tunnel. Many studies have been conducted to identify causes but the evidence is not clear. Various results published in the 1990's found strong associations between the prevalence of CTS and forceful and repetitive wrist movements such as work on keyboard and computers. However, more recent research has cited genetics and obesity as possibly larger factors than use, and has encouraged caution in ascribing causality.

Pregnant women, especially those in their third trimester, may experience hand pain and discomfort, for example, numbness, tingling sensation, or aching in the hands and wrists, particularly at night when bodily fluids are more equally distributed throughout the body and not just in the lower extremities. Because pregnancy causes swelling in many parts of the body, extra pressure may be present on the nerves in the hands and wrists, including the median nerve.

The only scientific established disease modifying treatment is surgery to cut or divide the transverse carpal ligament. However, one study found that within two years of surgery, 75% of the patients showed recurrence of pain symptoms. Moreover, surgery has many risks and is not suitable for temporary CTS, such as that experienced by pregnant women. Palliative treatments for CTS include use of night splints and corticosteroid injection. Other nonsurgical treatment methods include hand braces, exercises, ergonomic equipment, oral diuretics and nonsteroidal anti-

inflammatory drugs (NSAIDs). Websites including www.mycarpaltunnel.com discusses different treatment options. Other approaches include gloves, such as described in U.S. Pat. No. 6,006,751 and the prior art cited therein. Obviously, such gloves may be relatively expensive and are not disposable. Gloves may also limit manual dexterity and tactile sensitivity.

Kinesio tape has also been used as a nonsurgical treatment for CTS. Conventional kinesio tape is manufactured from a highly elastic strand wrapped in cotton fibers. It is employed as a gentle stretching therapy for soft tissue disorders and repetitive strain injuries. Kinesio tape has elasticity intended to match that of a person's skin, muscles, cartilage and connective fascia tissue. However, there are many different methods of taping around the hand and wrist and improper taping may cause further discomfort or even further damage to the median nerve. Moreover, proper taping often requires the use of two hands making it difficult if not impossible for a patient to apply the tape without assistance.

Hand braces and splints and temporary, removable devices worn on the hand are also known, for example, a stretching hand device described in U.S. Pat. No. 6,315,748 and sold under the mark THE CARPAL SOLUTION. The device includes a central, resilient, stretchable tensioning segment with a plurality of relatively less stretchable adhesive straps secured to the segment. In use, the segment is placed on the back of a patient's hand, whereupon the straps are pulled and adhered to the patient's palm in a fashion to expand the segment. In this orientation, the control segment exerts continuous yielding or tensile forces through the straps which in turn reduces carpal tunnel syndrome nerve compression and alleviates symptoms.

Another severe condition suffered by a significant portion of the population is migraine headaches. The pain of migraine occurs when excited brain cells trigger the trigeminal nerve to release chemicals that irritate and cause swelling of blood vessels on the surface of the brain. These swollen blood vessels send pain signals to the brainstem, an area of the brain that processes pain information. The pain of migraine is referred pain that is typically felt around the eye or temple area.

In addition to prescription and over-the-counter drugs, there are many remedies for migraines, including sleeping, taking caffeine, ice packs, and avoiding sunlight or certain foods. Kinesio tape has also been used to alleviate severe headaches. Experts believe that taping can significantly help reduce headaches by repositioning the muscles that are under stress and therefore helping to relieve tension in the neck.

Indeed, the adhesive tape or strips have many medical uses and applications beyond bandaging wounds. For example, nasal snoring strips are pieces of elastic plastic that are embedded in a sticking plaster for attachment across the outside of the nose. Shape-memory causes the plastic to straighten which effectively widens the nasal passages to allow for improved airflow. These strips are disposable and simplistic in design, construction and use.

Accordingly, there is a desire for a device that can reduce the symptoms of pressure-related conditions and ailments, including CTS and migraines. There is also a desire for the device to be simplistic in design, construction and use and be able to lift skin above a sensitive underlying site.

SUMMARY OF THE INVENTION

The device of the present invention is primarily intended for use in those suffering from Carpal Tunnel Syndrome

(CTS), but also has application for relieving migraine headaches and other situations where lifting the skin and tissue above a sensitive underlying site would provide benefits.

The present invention provides for an inexpensive, reliable and easy to use device which lifts an area of skin upwardly in a direction generally perpendicular to the skin surface. It does not interfere with the sleep of the user and is a low cost disposable item. In a preferred embodiment, used for CTS, the device comprises a thin, generally rectangular member with a long dimension and a short dimension. The member is made from a plastic material, with "shape memory", which in its normal configuration is generally flat. When pressure is applied orthogonally to the member, the member deforms. When released from pressure, the "shape memory" member has spring and rebounds to its normal configuration as much as possible. On a bottom (skin-facing) surface of the device, adhesive or adhesion member (used interchangeably herein) is provided on at least part of a central portion. A removable protective cover (e.g., release liner of wax paper) is applied over the adhesive.

In use, the protective cover is removed and the adhesive is applied to the palm proximate the wrist by a force depressing the center portion of the member toward the palm and fixes the center portion of the member to the palm. The member is oriented with the long dimension of the member across the palm between the thumb and the pinky finger. Since the adhesive is applied to a concave portion of the palm, the device forms a bridge across the palm. Side portions of the member supporting the center portion are not adhered to the palm so they can slide freely in contact with the palm. The skin of the palm adhering to the adhesive of the member is pulled upwardly as a result of negative pressure when the member is released and rebounds with its "shape memory".

The adhesive can be applied to the device by any conventional means so that the adhesive remains on the member when the protective backing is removed. Alternatively, the adhesive can be applied by a user directly to the member or to the palm or skin of the user. Lifting and/or stretching the skin in the area of the palm or treatment site relieves symptoms, including the symptoms of CTS.

While a preferred embodiment envisions use of a single piece of spring-type plastic material, it is possible to incorporate other designs to provide a resilient or shape-memory member, such as synthetic whalebone, polyester boning material, metal, metal alloys, such as nitinol, and the like.

Accordingly, the present invention is directed a therapeutic device adapted for application to skin covering a treatment site on a patient's body, having a generally rigid but elastically deformable body with at least one support portion and a bridge portion, the support portion adapted to rest on the skin, the bridge portion having an adhesive adapted to adhere to at least a portion of the skin, wherein the body is adapted to assume a neutral configuration with the adhesive and the portion of the skin separated by an air gap, and an adhesion configuration with the portion of the skin adhering to the adhesive being lifted and/or stretched at the treatment site. The body is also adapted to assume a depressed configuration the wherein the body is deformed from the neutral configuration with the bridge portion being depressed to bring the adhesive into contact with the portion of the skin.

The body while in its neutral configuration supports the bridge portion at a highest elevation relative to the skin surface of the treatment site, where as the body while in its depressed configuration supports the bridge portion at a lowest elevation. Moreover, the body while in its adhesion configuration supports the bridge portion at an in-between elevation greater than the lowest elevation and lesser than the greatest elevation. The adhesive provided on an inner, skin-facing surface may include a coating or layer of adhesive material, double sided adhesive tape, at least one suction cup, and/or micro-suction cup tape.

In a more detailed embodiment, the therapeutic device has a thin sheet body with a "butterfly" configuration wherein the support portion supporting the bridge portion includes side planar portions adapted to rest on the skin. The butterfly configuration is well-suited for application to a palm of the patient's hand with the device positioned on the palm and the bridge portion longitudinally aligned with a median nerve of the palm. The adhesive is adapted for adhesion to skin below the device and above the median nerve.

The thin sheet body may also be configured rectangularly with rounded corners and one or more curved edges. As such, the device is also adapted for application on other areas of the patient's body. The rounded corners are atraumatic and the curved edge(s) accommodate features, curves and contours of the face or body, for example, nose, eyes, knuckles, elbows, knees and ankles.

In another more detailed embodiment, the therapeutic device has a thin sheet preformed body having an outer surrounding rim and a raised center bridge portion. The rim and the bridge portion may have a common shape, for example, circular, rectangular, square or polygonal. The bridge portion is supported by at least three legs extending upwardly from the rim. The preformed body is well-suited for application to a forehead, e.g., a temple region, of the patient. Each leg may be L-shaped including a radial leg portion and an axial leg portion. The radial leg portion extends between the bridge portion and the axial leg portion, and the axial leg portion extends between the radial leg portion and the outer rim.

In accordance with a feature of the present invention, the body of the device may have one or more predetermined curvatures in one or more directions. The curvature(s) serve to ensure that the bridge portion is elevated and separated from the skin below by an air gap when the device in its normal or neutral configuration. The curvature(s) also serve to strengthen the bridge portion against the pull of the adhered skin when the device has been depressed and applied to the treatment site and allowed to rebound to or toward its neutral configuration under its body's shape memory. In a more detailed embodiment, the bridge portion of the device has a curvature or concavity in at least one direction toward the inner, skin-facing surface.

The device may also be configured as a flexible band or sleeve or semi-rigid cuff to be worn on an appendage. The body is adapted to encircle or wrap around the appendage, e.g., an arm or a leg, with an inner, skin-facing surface having at least two projections or ridges with an adhesive positioned therebetween for adhesion to the skin, wherein the skin is lifted when adhered to the adhesive.

The present invention also includes a method and system for manufacturing the aforementioned therapeutic device. The manufacturing process includes:

1. A sheet of plastic material is passed through a heating tunnel to flatten or smooth the material.

2. The material is passed through rollers, for example, silicone coated rollers, to curve the material with a desired radius.

3. The material is passed through an adhesive applicator which applies adhesive, including adhesive tape, with or without a release liner.

4. The material is passed through a cutting chamber, for example a die set, which cuts bodies of the devices out of the material.

Sequence of the above steps may be varied as desired or appropriate.

The method of manufacturing may also include custom-fitting the therapeutic device by making a mold of a body part to be fitted with the device and customizing the die set to the mold.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings. It is understood that selected structures and features have not been shown in certain drawings so as to provide better viewing of the remaining structures and features.

FIG. **1** is a perspective view of a hand with a cross-sectional view of a proximal portion including a median nerve and a carpal tunnel.

FIG. **2**A is a top plan view of a therapeutic device, in accordance with one embodiment of the present invention.

FIG. **2**B is a bottom plan view of the therapeutic device of FIG. **2**A.

FIG. **2**C is a lateral cross-sectional view of the therapeutic device of FIG. **2**A, taken along line C-C.

FIG. **2**D is a longitudinal cross-sectional view of the therapeutic device of FIG. **2**A, taken along line D-D.

FIG. **3** is a top plan view of the therapeutic device of FIG. **2**A, as applied to a user's palm.

FIG. **3**A is a cross-sectional view of the therapeutic device of FIG. **2**A, in a neutral configuration.

FIG. **3**B is a cross-sectional view of the therapeutic device of FIG. **2**A, in a depressed configuration.

FIG. **3**C is a cross-sectional view of the therapeutic device of FIG. **2**A, in an adhesion configuration.

FIG. **4**A is a top plan view of a therapeutic device, in accordance with another embodiment of the present invention.

FIG. **4**B is a bottom plan view of the therapeutic device of FIG. **4**A.

FIG. **4**C is a lateral cross-sectional view of the therapeutic device of FIG. **4**A, taken along line C-C.

FIG. **4**D is a longitudinal cross-sectional view of the therapeutic device of FIG. **4**A, taken along line D-D.

FIG. **5**A is a top plan view of a therapeutic device, in accordance with another embodiment of the present invention.

FIG. **5**B is a bottom plan view of the therapeutic device of FIG. **5**A.

FIG. **5**C is a lateral cross-sectional view of the therapeutic device of FIG. **5**A, taken along line C-C.

FIG. **5**D is a longitudinal cross-sectional view of the therapeutic device of FIG. **5**A, taken along line D-D.

FIG. **6** is a top plan view of the therapeutic devices of FIGS. **4**A and **5**A, as applied to a forehead of a user.

FIG. **7** is a schematic diagram of a system implementing a method of manufacture in accordance with an embodiment of present invention.

FIG. **7**A is a perspective view of a machine system for manufacturing and packaging the therapeutic device of FIG. **2**A, in one stage of operation in accordance with an embodiment of the present invention.

FIG. **7**B is a perspective view of the machine system of FIG. **7**A in another stage of operation in accordance with an embodiment of the present invention.

FIG. **8**A is a perspective view of a therapeutic device, in accordance with another embodiment of the present invention.

FIG. **8**B is a top plan view of the therapeutic device of FIG. **8**A, in a neutral configuration.

FIG. **8**C is a bottom plan view of the therapeutic device of FIG. **8**A.

FIG. **8**D is a cross-sectional view of the therapeutic device of FIG. **8**B, taken along line D-D.

FIG. **8**E is a cross-sectional view of the therapeutic device of FIG. **8**A, in a depressed configuration, as applied to skin.

FIG. **8**F is a cross-sectional view of the therapeutic device of FIG. **8**A, in an adhesion configuration, as applied to skin.

FIG. **8**G is a cross-sectional view of a therapeutic device, in accordance with another embodiment of the present invention.

FIG. **9** is a top plan view of the therapeutic device of FIG. **8**A, as applied to a temple region of a user.

FIG. **10** is a schematic diagram of a system for implementing a method of manufacturing a therapeutic device in accordance with another embodiment of the present invention.

FIG. **11** is a perspective view of a therapeutic device in accordance with another embodiment of the present invention.

FIG. **12** is a perspective view of the devices of FIGS. **11** and **14**, as applied to forearm of a user.

FIG. **13** is a perspective view of the device of FIG. **11**, as applied to a thigh and a foot of a user.

FIG. **14** is a perspective view of a therapeutic device in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a device having a bridge portion adapted for releasable adherence to a patch of skin so as to lift the patch of skin above a sensitive underlying treatment site in reducing discomfort or pain associated with tissue compression at the treatment site. The device is positioned on the patient such that the bridge portion is elevated above the treatment site in a direction generally perpendicular to the patch of skin with an exposed adhesive facing the patch of skin to be lifted and/or stretched outwardly. With the application of pressure to elastically deform the device from its original neutral configuration, the bridge portion is brought into contact with the patch of skin, adhering the skin to the adhesive. When the pressure is removed, the device rebounds and generally reassumes its original configuration with the bridge portion lifting the attached patch of skin as it returns to an elevation at or near its original elevation.

With reference to FIGS. **2**A-**2**D, a device **200** has a thin sheet body **202** with a longer length dimension L and a shorter width dimension W. The body **202** has an outer surface **204** and an inner (skin-contacting or skin-facing) surface **206**. The body **202** may be constructed of any suitable material with "memory" such that the body can be deformed under application of a force or load from an original shape or configuration and elastically return to the original shape or configuration after removal of the force or load. Depending on the underlying material of which the body **202** is constructed, the body **202** may have a thickness

T ranging between about 0.012 and 0.018 inches (0.30 mm-0.45 mm), and preferably about 0.015 inches (0.40 mm). The body **202** may also be provided with one or more predetermined curvatures C, such as concavity or convexity, in one or both axes L and W.

Suitable materials for the body **102** include materials that are biocompatible or FDA-approved plastics, acrylate, polymers, metal, such as aluminum or stainless steel, or even wood or wood composites. A presently preferred material is polyethylene terephthalate (PET).

For use of the device **200** to treat the symptoms of CTS, the thin sheet body **202** of the device has a "butterfly" configuration adapted affixation to a palm **113** of a user, as illustrated in FIG. **3**. The body **202** of the device **200** has two larger side support portions or "wings" **220** and an elevated bridge portion **208** extending between the support portions **120**. The body **202** spans between about 1½ inches and 1¾ inches, and preferably about 1¼ inches in the direction of the shorter/width dimension or axis W, and about 2½ inches and 2¾ inches, and preferably about 2¼ inches in the direction of the longer/length dimension or axis L.

The bridge portion **208** is rectangular, being elongated along the axis W and spanning about ⅜ inch in the L axis. Each of the wings **220** has a rounded "petal" shape with a greater outer width **221** that tapers slightly to a lesser inner width **222** adjacent the bridge portion **208**.

Moreover, the body **202** is provided with at least one predetermined curvature relative to an axis to conform to contours of the palm **113** near the wrist and location of the carpal tunnel (FIG. **1**). In the illustrated embodiment of FIGS. **2**C and **3**, the body **202** has a predetermined concavity in the axis W toward the inner surface **206** to correspond with the convexity at the proximal end of the palm **113** (FIG. **1**). The predetermined concavity of the body relative to the axis W may generally trace a circle defined by a radius R ranging between about 4 to 6 inch diameter, preferably about a 5 inch diameter.

The inner surface **206** of the bridge portion **208** is provided with an adhesion member or adhesive **226**, for example, a coating or layer of adhesive for releasably affixing the device **200** to the palm. The adhesive **226** is covered and protected by a release liner **228** that is removed prior to use of the device **200** and application onto the user's skin.

With reference to FIGS. **3** and **3**A-**3**C, use of the device **200** is described as follows. After the release liner **228** has been removed to expose the adhesive **226**, the device **200** is placed over the palm **113** with the inner surface **106** and the adhesive **226** facing the palm **113**. The device **200** is oriented with its longer axis L being generally transverse to middle finger **114**. As shown in FIG. **3**A, the device is positioned with each wing **220** resting on a respective convexity of the palm near muscles **102** and **104**. With the device in its original and neutral configuration, the bridge portion **208** spans linearly in between the muscles **102** and **104**, and elevated from the recess **112** and the median nerve **118**. Advantageously, the slight but predetermined concavity of the device **100** in the lateral or W axis (FIG. **2**C) enables the device to conform to the convexity of the palm **113**, with the bridge portion **108** being elevated and separated from the skin below by an air gap G. As shown in FIG. **3**B, to apply the device, pressure P is then applied, for example, by the user's other hand or that of an assistant, to the outer surface **204** of the bridge portion **208** above the adhesive **226** toward the skin so as to deform the bridge portion **208** (and any other portions of the body **202**), bring the adhesive **226** into contact with the skin and allow the adhesive **226** to adhere to the skin, reducing or eliminating the air gap G.

When the pressure P is removed and the body **202** is released, the elastically deformable body **202** generally returns to its original neutral state in reassuming the predetermined concavity and the linearity between the bridge portion **208** and the wings **220**, with at least a portion of the skin of the recess **112** adhering to the adhesive **226**, as shown in FIG. **3**C. Advantageously, the linearity or "bridging" of the bridge portion **208** when the body **202** rebounds pulls the adhered skin and adjacent tissue in the region of the recess **112** outwardly or away from the median nerve **118** to result in negative pressure and reduction of compression of the median nerve. In accordance with a feature of the invention, the lifted skin or tissue may be raised or repositioned from its original position a distance ranging between 1.0 mm to 5 mm, preferably 2.0 mm to 4.0 mm, and more preferably about 3.0 mm. To that end, the concavity of the body **202** which extends across the bridge portion **208** further strengthens the bridge portion **208** when lifting the skin against the pull of adjacent skin. Moreover, opposing ends **208**E of the portion **208**, each with three sides unattached to the body **102**, allow the device **200** to be more flexible and comfortable while affixed to the palm, while providing additional bridging strength to the bridge portion **208** against the pull of adjacent skin, as well as providing additional surface area for the adhesive **226** to adhere with the skin.

In the disclosed embodiment, the bridge portion **208** is adhered to the skin, whereas the wing portions **220** are without adhesive and are not attached but are free to move and slide relative to the skin. This freedom of movement increases comfort to the user of the device by minimizing pinching or poking that may otherwise resulting discomfort if the wing portions (or any portions thereof) were also adhered to the skin. In that regard, a layer of fabric or liner or a coating of friction reducing gel may be provided on the inner surface of the wings **220** to prevent chafing. However, it is understood that the adhesive and adhesion member may be applied to one or more regions on the inner surface of the body and configured to cover beyond the bridge portion, for example, all or portion(s) of each or both wings **220**.

It is understood that the bridge portion **208** need not be centered between the wing portions **220**. That is, the size and/or shape of each wing **220** need not be equal or matching to the other. One wing may be larger, wider and/or longer than the other, as need or appropriate. There need not be symmetry about the axis L or W.

In an alternative embodiment of the present invention, a device **300** to treat the symptoms of a migraine headache is illustrated in FIGS. **4**A-**4**D. Similarities between the devices **200** and **300** (as well as other devices described herein) are denoted by similar reference numerals. However, each device has different adaptations for application and affixation to the patient's body. For example, the device **300** has adaptations for application and affixation to a generally flat skin site such as forehead **130** (FIG. **6**), although it is understood that the device **200** may also be used to treat migraine headaches. A body **302** of the device **300** has a generally rectangular configuration with rounded corner **340**, and a bridge portion **308** contiguous with two opposing rectangular or square side support portions **320**. The body **302** spans between about ¾ inches and 1-¼ inches, and preferably about 1.0 inches in the direction of the shorter/width dimension or axis W, and about 2.0 inches and 2-½ inches, and preferably about 2-¼ inches in the direction of the longer/length dimension or axis L. The bridge portion

308 is rectangular, being elongated relative to the axis W and spanning about ⅜ inch in the L axis.

The body **302** has at least two predetermined curvatures (same or different degree of curvatures), one in the axis W (FIG. **4**C) and another in the axis L (FIG. **4**D), to provide concavity toward the inner surface **304** in at least two directions.

In another embodiment of the present invention for treatment of migraine symptoms, especially in the center of the forehead above the nose as illustrated in FIG. **6**, a similar device **300'** of FIGS. **5**A-**5**D may have one or more arcuate longitudinal edges **342** which can accommodate placement of the device around eyes, nose or ears.

For either device **300** or **300'**, inner surface **304** of the bridge portion **308** is provided with adhesion member or adhesive, which may include one or more suction cups **330** (FIGS. **4**A-**4**D) or micro suction cup tape **332** (FIGS. **5**A-**5**D) having a surface with a multitude of microscopic craters **334** that work by creating many partial vacuums between the tape and target surface. The tape **332** can rebond repeatedly, and leaves no residue on the skin. A preferred tape is No. MSX-6800, DC Conformable Hi-Tack Type tape manufactured by 3M.

Moreover, for either device **300** or **300'**, on the inner surface **306** at or near lateral edges **344**, each side support portion **320** includes a projection, such as a raised ridge **346** with a height H (FIGS. **5**A-**5**B) which elevates the body **302** away from the skin so that the bridge portion **308** forms a bridge that is separated from the skin with an air gap in between. In that regard, the body **302** has sufficient rigidity to provide linearity between the portions **308** and **320**. Each ridge **346** may have a different height, depending on the contour of the site. The ridges **346** may be constructed of the same material as the body **302** or of any other suitable material that provides sufficient form and structure to lift the body **302**. Where the body **302** spans about 1-7/16 inches along the axis L, and about 1-3/16 inches along the axis W, each ridge **346** may have a thickness of about 3/16 inch and a width ranging between about ⅛ inch and ¼ inch. Ends of each ridge may terminate a distance of about ⅛ inch from the longitudinal edges **240**.

It is noted that the concavity/ies of the bodies (actual or as effectuated by the ridges **346**) should be of a sufficient degree such that peripheral edges, including longitudinal edges **340** and lateral edges **344** extend beyond the adhesive (e.g., adhesive coating, adhesive tape, suction cups, or micro-suction cup tape) so as to elevate the adhesive from skin and provide an initial air gap before the skin is adhered to the device (as shown in FIGS. **4**C, **4**D and **5**D).

In use, the adhesive **326** is exposed and the device **300'** is placed over the target skin site with the inner surface **304** and the adhesive **326** facing the skin. The device **300** is oriented with the ridges **346** straddling the skin site so that the bridge portion **308** and the adhesive **326** is directly over the sensitive skin site. Elevated by the ridges **346**, the bridge portion **308** is situated above the skin, separated by an air gap. With the device so positioned, pressure is then applied by the user (or an assistant) to the outer surface **306** of the bridge portion **208** directly above the adhesive **326** toward the skin so as to deform the bridge portion **308** (and any other portions of the body **302**), bring it into contact with the skin and allow the adhesive **326** to adhere to the skin.

When the pressure is removed and the body **302** is released, the elastically deformable body **302** generally returns to its original neutral state in reassuming the linearity between the bridge portion **308** and the side portions **320**, thereby lifting the adhered skin and tissue and reducing compression at the site. The device can be situated around the eyes, near a temple, or above the nose on the forehead, as facilitated by the arcuate longitudinal edges **240**, as shown in FIG. **6**.

With reference to FIG. **7**, the foregoing devices may be manufactured in accordance with the following method:

1. Providing a single flat sheet **150** of suitable material;

2. Heating the sheet to smooth the sheet **150** and remove wrinkles and bends;

3. Stamping, die-cutting or otherwise cutting the sheet **150** to form the device.

4. Applying the adhesive to the inner surface of the bridge portion.

The method may include forming the sheet **270** with at least one predetermined curvature.

Heating the sheet may include passing the sheet **170** through a heat tunnel **151**, and/or under or between heated roller(s) **152**. Forming the sheet **150** with at least one predetermined curvature may include passing the sheet through heated roller(s) **154**. Stamping, die-cutting or otherwise cutting the sheet into device bodies may be performed by a die set including roller **154** and a movable punch **156**. The movable punch **156** may be curved to conform to the curvature of the roller **154** to simultaneously form the device body with at least one or more predetermined curvature. Applying the adhesive **326** may occur at any stage, including before, during or after stamping, die-cutting or otherwise cutting the sheet. As mentioned, the adhesive may be medical grade adhesive suitable for topical use. It may take the form of a solid coating or layer (or a plurality of adhesive lines), double-sided adhesive tape, suction cup(s) or micro-suction cup tape. Any release liner may be applied simultaneously with the application of the adhesive or afterwards.

Where the device has ridges **246**, the die set may have formations to stamp the ridges into the sheet, or they may be mounted after stamping. Alternatively, the method of manufacture may include applying or adhering the ridges **246** to the inner surface of the bridge portion before, during or after application of the adhesive to the inner surface.

An embodiment of a machine system **160** implementing a method of manufacture and packaging of the device is illustrated in FIGS. **7**A and **7**B. The machine system **160** includes a longitudinal conveying platform **161** that defines a conveying pathway P from a first end **162** downstream to a second end **164**. At or near the first end **162** is dispenser roller **166** of sheet material **167**. Stored in roll form, the sheet material advantageously has a preformed curvature. To that end, the dispenser roller **166** in one embodiment of the invention has an initial diameter no greater than about 25 inches and more preferably no greater than about 20 inches.

Downstream of the dispenser roller **166** is a smooth roller **168** positioned to flatten the sheet material and remove wrinkles or bumps. Downstream of the smooth roller **168** is an adhesive tape applicator roller **172** which applies double-sided adhesive tape strips **174** onto an upward surface **175** of the sheet material (which becomes the inner/skin-facing surface of the device). The tape strips **174** are mounted on the applicator roller **172** with an exposed adhesive surface **171** facing outwardly so that it contacts and affixes to the upward surface **175** of the sheet material **167** upon pressure applied by the roller **172**. Release liner strips **173** are affixed to the opposing surface of the applied tape strips **174** for subsequent removal by users when applying the devices.

Downstream of the applicator roller **172** is a die press **179** with upper platen **176** and lower platens **178**A and **178**B driven by air hydraulics assembly **180**. The upper platen **176**

is driven toward first lower platen **178**A in a first stage operation of the die press and toward the second lower platen **178**B in a second stage operation of the die press, as described below, to die cut a plurality of individual devices **10**A and **10**B from the sheet material **167** and the tape strips **174** affixed thereon.

The lower platens **178**A and **178**B are supported on a carrier **182** that is adapted for translational movement in opposition directions T**1** and T**2** along a pathway generally transverse to the conveying pathway P. In a first stage operation (FIG. **7**A), the carrier **182** slides in direction T**1** to position the first lower platen **178**A directly below the upper platen **176** wherein the upper platen **176** engages the first lower platen **178**A and cuts devices **10**A in die recesses **181**A, exposing the second lower platen **178**B off one side of the conveying platform **161** and rendering it accessible to a transport member **184**B. In the second stage (FIG. **7**B), the carrier **182** slides in direction T**2** to position the second lower platen **178**B directly below the upper platen **176**, wherein the upper platen **176** engages the second lower platen **178**B and cuts devices **10**B in die recesses **181**B, exposing the first lower platen **178**A off the opposite side of the conveying platform **161** and rendering it accessible to an opposing transport member **184**A. Accordingly, the carrier **182** translates each lower platen **178**A and **178**B between an engagement position under the upper platen **176** and an unload position under respective a transport member **184**A. Where a full die cut cycle of the die press involves the first stage operation followed by the second stage operation in sequence, the hydraulics assembly drives the die press **179** and carrier **182** in a manner whereby one of the lower platen is placed under the upper platen **176** for die cutting and while the other lower platen is exposed and accessible to a respective transport member **184**. That is, in one stage of operation, the one lower platen is in the engagement position whereas the other lower platen is in the unload position, and in the other stage of operation, the other lower platen is in the engagement position whereas the one lower platen is in the unload position.

In addition to driving the die press **179** and the carrier **182**, the hydraulics assembly **180** also drives support arms **185** to move the transport members **184**A and **184**B between at least three positions: a wait position, a load position, and an off-load position. The transport members are adapted to secure a load of devices and transport the devices from the lower platens **178**A and **178**B to packaging or dispensers **183** arranged on tray members **186**A and **186**B arranged below the lower platens in their exposed positions. As shown in FIG. **7**A, when lower platen **178**B is exposed and accessible to transport member **184**B, the transport member **184** is actuated by the hydraulics assembly **180** to move from its wait position to the load position where it picks up devices **10**B from the lower platen **178**B. In the illustrated embodiment, the transport member **184** includes grippers with vacuum/suction cups **189** mounted on posts **190** which are activated to grab the devices **10**B individually. With a load of devices on board, the transport member **184**B is actuated by the hydraulics assembly **180** to move into the off-load position toward the tray member **186**B positioned below the exposed position of the lower platen **176**B and release the devices **10**B into dispensers **183**B. The transport member **184**B is then returned to its wait position for the next cycle when the lower platen **176**B contains more cut devices and is exposed and accessible again.

The tray member **186**B is supported on carrier **188**B which translates the tray member **186**B along direction C parallel with the conveying pathway P so that the tray member **186**B can shift between different positions for efficient loading of the dispensers **184**. In the illustrated embodiment, the tray member is translated between two positions: a proximal position and a distal position.

It is understood that the actuation and movement of the die press **179**, the carrier **182**, the transport members **184**A and **184**B and the carriers **188** may be coordinated and synchronized with each other, as desired or appropriate for efficient operation of the machine system. For example, the upper platen **176** may be driven to engage lower platen **178**A as the support arm **185**B is driven to pick up devices **10**B from the lower platen **178**B, and as the support arm **185**A is releasing devices into the dispensers **181**A. A suitable system and machine for transporting work pieces is described in U.S. Pat. No. 8,230,989, entitled SHUTTLE MACHINE FOR MACHINE TOOL, the entire contents of which are hereby incorporated by reference.

The spent sheet material **167** downstream of the die press **179** is drawn downstream by a servo drive rollers **190** and collected on a waste roller **192** at the second end **164** of the conveying platform **161**.

Another embodiment of the present invention is illustrated in FIGS. **8**A-**8**C. A device **400** has a thin sheet body which has been formed with a raised center profile. The body has a support portion **402** and an elevated planar center bridge portion **408**. The support portion **402** is adapted to rest on skin above a sensitive underlying site, such as temple **132**, as shown in FIG. **9**. The support portion **402** includes an outer rim or base **450** and radially extending L-shaped legs or posts **454** projecting therefrom that connect the base **450** and the bridge portion **408**. The base **450** is adapted to rest on and generally surround skin of a sensitive underlying site, such as temple **132**, as shown in FIG. **9**. Between adjacent pairs of legs is an opening **456**. As better seen in FIGS. **8**D-**8**F, each leg has a radial portion **460** coplanar with the bridge portion **408** and an axial portion **462** extending between the radial portion and the base **450**. The axial portion **462** may extend at an angle ranging between about 45 to 120 degrees, preferably about 60 to 100 degrees, and more preferably about 90 degrees, from the base **450**. The plurality of legs **454** ranges between about two and five.

With reference to FIGS. **8**A-**8**F, the illustrated embodiment of the device has three legs **454** positioned equidistance from each other (e.g., centered at about 0, 120 and 240 degrees), and three openings **456**. Moreover, each leg presents a 90 degree angle between the radial portion **460** and the axial portion **462**, and also between the axial portion **462** and the base **450**. Width of the legs can vary depending on the plurality of legs and the desired flexibility of the bridge portion **408**. An inner surface **406** of the bridge portion **408** has an adhesion member or adhesive **426**, for example, a coating or layer of adhesive, an adhesive tape or a micro suction cup tape, as described above. An inner surface of the base **450** may also be provided with an adhesion member or adhesive to help secure the device on the skin.

In one embodiment, the outer radius r of the base **450** is 1.375 inches, the radius R of the bridge portion **408** is 0.5 inch, the width WA of the axial portion **462** is 0.625 inch, and the width WB of the base **450** is 0.125 inch. The height H of the bridge portion **408** from the base **450** is 0.1875 inch and the thickness of the body **402** throughout the device **10** is 0.015 inch.

The base **450** and the bridge portion **408** may each be any shape, for example, rectangular, polygonal, oval, or circular. In the illustrated embodiment, both the base and the bridge portion are circular.

In use, the adhesive **426** is exposed and the device **400** is placed over the target skin site with the base generally surrounding the site and the adhesive **426** facing the skin and tissue, as shown in FIG. **8**D. Elevated by the legs **454**, the bridge portion **408** is situated above the skin, separated by an air gap generally equal to the height H. With the device so positioned, pressure P is applied by the user (or an assistant) to the outer surface **404** of the bridge portion **408** toward the skin so as to deform the upper body **452** (including the bridge portion **408** and/or any of the legs **454**), bring the bridge portion **408** into contact with the skin and allow the adhesive **426** to adhere to the skin, as shown in FIG. **8**E.

When the pressure is removed and the upper body **452** is released, the elastically deformable body **402** rebounds and generally returns to an elevation at or near its original elevation wherein the bridge portion **408** lifts the adhered skin and tissue and reducing compression at the site.

As shown in FIG. **8**D, the bridge portion **408** and the radial leg portion **460** may extend perpendicularly relative to the axial leg portion **462**, or the portions **408** and **460** may have at least one predetermined curvature in a direction. As illustrated in FIG. **8**F, device **400'** has an upper body **462'** with curvature in more than on axial direction to provide a concavity toward the inner surface **406** that forms an elevated dome.

The devices of the present invention may be worn at all times, or only a specified time periods, such as night time, during sleep. Each device may be reused so long as the adhesive is functional. If not, the device may be discarded, or new adhesive may be applied to the device over or in place of the spent adhesive. Due to the inexpensive cost of the device and its components, the device may be economically discarded as trash or for recycling.

With reference to FIG. **10**, the device **400** can be manufactured as follows:

1. Forming the device;

(a) Injection, press or vacuum forming the base **450**, bridge portion **408** and the legs **454**; or

(b) Providing a single flat sheet **470** of suitable material;

(i) Heating the sheet to smooth the sheet **370** and remove wrinkles or bends;

1. Heating by passing through a heat tunnel **471**; and/or

2. Heating by heated roller(s) **472**.

(ii) Stamping, die-cutting or otherwise cutting sheet to form the base **450**, the bridge portion **408** and the legs **454**;

1. Die punching out the openings **456** to form the legs with die set **473**;

2. Applying the adhesive **426** to the inner surface **406** of the bridge portion **408**.

The stamping, die-cutting or otherwise cutting of the sheet may include both cutting of the base **450**, bridge portion **408** and legs **454** from the sheet and reforming/reshaping to provide the curvature of the upper body **452** and/or angulation or bend in the leg **454** for elevating the bridge portion **408** from the base **450**. The application of the adhesive **426** may occur before, during or after stamping, die-cutting or otherwise cutting of the sheet.

In yet another embodiment of the present invention, a device **500** may be worn as a band or sleeve encircling a limb or a portion thereof. With reference to FIG. **10**, the device **500** is elongated defining a length axis L and a width axis W. The device **500** has a generally rigid yet flexible main body **511** having a planar, generally rectangular form, and two fastening side portions **513**, each having a generally rectangular form and adjoined to an opposing side edge **515** of the main body **511**. The main body **511** may be constructed of the same aforementioned suitable materials. The side portion **513** may be constructed of an elastic, stretchable material or fabric. On an inner surface **506** of the main body **511**, an adhesion member **526** is provided and situated between at least two projections **546** defining an elevated bridge portion **508**.

In use, the device **500** is positioned on a limb, for example, a forearm (FIG. **12**), a thigh or a foot (FIG. **13**), with the exposed adhesion member **526** and projections **546** facing the skin above the treatment site. The side portions **513** are wrapped around the limb and releasably fastened to each other by fasteners **517**, e.g., hook and loop fasteners, eye and hook fasteners, snap fasteners, etc. The device **500** in a neutral configuration presents the bridge portion **508** at an elevated position above the skin, the two separated by an air gap. When pressure is applied to outer surface **504** of the bridge portion **508**, the device assumes a deformed configuration so that the adhesion member comes **526** into contact with the skin. When the pressure is removed, the device rebounds and the skin is lifted by the bridge portion. The device **500** may have a slight predetermined curvature or concavity in the L axis toward the inner surface **506** to better conform to the limb.

In a further embodiment of the present invention, a device **500'** may be worn as a cuff on the wrist, as shown in FIG. **12**. The device **500'**, as illustrated in FIG. **11**, has a construction similar to that of the device **500** of FIG. **10**, except that the device is smaller and has a pronounced predetermined curvature or concavity in the L axis toward the inner surface **506** to better conform to the wrist.

The present invention also includes a method of manufacturing a custom-fitted therapeutic device, wherein a mold of the treatment site, e.g., a palm, a forearm, a thigh, is made and a die set for manufacturing the device is customized according to the mold.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. As understood by one of ordinary skill in the art, the drawings are not necessarily to scale. Dimensions of the devices may be modified to fit different sized users. As noted above, the device may have more than one adhesive or adhesive member which may be applied to different areas of the device beyond the bridge portion. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

1. A method for reducing hand and wrist pain experienced by a patient having carpal tunnel syndrome comprising:

(a) providing a device adapted for lifting skin at a treatment skin at a treatment site on a patient's body comprising a generally rigid but elastically deformable body comprising:

two support wings comprising top and bottom surfaces wherein the bottom surfaces of the support wings are free of adhesive;

a bridge portion comprising top and bottom surfaces wherein the bottom surface has a layer of adhesive

over at least a portion thereof, the adhesive having an exposed bottom contact surface;

(b) positioning the body on the palm of the patient's hand such that the bridge portion is longitudinally aligned with a median nerve of the hand and is at an elevation above and spaced apart from the skin surface such that there is an gap between the skin surface and the bottom contact surface of the adhesive; and

(c) applying downward pressure to the top surface of the bridge portion from a neutral configuration so that the adhesive contacts the skin above the meridian nerve; and

(d) removing the downward pressure to the top surface of the bridge portion; and

(e) wherein, when the downward pressure is removed, the bridge portion moves upwardly toward the neutral configuration a distance of from about 2 millimeters to about 4 millimeters thereby lifting the adhered skin surface at the treatment site.

2. The method of claim **1** wherein the device is generally planar is its neutral configuration.

3. The method of claim **1** wherein the each support wing comprises a peripheral edge which is curved.

4. The method of claim **1** wherein the body of the device has a generally uniform thickness of from about 0.3 to about 0.45 millimeters.

5. The method of claim **4** wherein the body of the device has a generally uniform thickness of about 0.4 millimeters.

6. The method of claim **1** wherein the thickness of the gap is at least 2 millimeters.

7. The method of claim **1** wherein the thickness of the gap is at least 3 millimeters.

8. The method of claim **1** wherein the adhesive layer comprises double sided adhesive tape.

9. The method of claim I wherein the adhesive layer comprises micro-suction cup tape.

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